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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,918	09/15/2003	Sean B. Carroll	OPHD-08258	2733

23535 7590 01/11/2008

MEDLEN & CARROLL, LLP
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EXAMINER	
KIM, YUNSOO	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
01/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/662,918	CARROLL ET AL.	
	Examiner	Art Unit	
	Yunsoo Kim	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-13 and 15-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-13,15-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/29/07 has been entered.

2. Claims 1, 3-13 and 15-20 are pending and are being examined.

3. Applicants' request filed on 10/29/07 to withdraw finality of the action mailed 8/22/07 has been considered. Applicants stated in the request that upon withdrawing of the 35. U.S.C.1121st paragraph, enablement rejection, the final rejection has truncated the Applicant's entitlement to a full and fair hearing.

However, the final action mailed on 8/22/07 was properly made because it did not introduce any new grounds of rejections but withdrew the 35. U.S.C.112, 1st paragraph, enablement rejection introduced in the office action mailed 1/25/07.

The rejection under 35.U.S.C. 103(a) has been introduced in 1/25/07 and maintained for the reasons set forth in the office action mailed 8/22/07 and no new references have been introduced. Applicant is deemed to interpret Examiner's statement "...claimed invention implicitly requires developing tolerance as well" on p.3 of action mailed on 8/22/07 as a new ground of reasoning. However, the statement was provided as an example as the inducing tolerance does not differentiate the claimed method from the referenced method. Therefore, the finality of the last office action is proper.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1 and 3-13 are rejected under 35 U.S.C. 103 as being unpatentable over U.S. Pat. No. 4,748,018 (IDS reference, of record), in view of Uemura et al. (Infection and Immunity, 1974, p. 470-471), of record, as is evidenced by Merck Manual of Diagnosis and Therapy (17th ed., 1999, p. 1176-1185), of record, for the reasons set forth in the office action mailed on 8/22/07.

Applicants' arguments and the declaration by Stafford filed on 10/29/07 have been fully considered but they were not found persuasive.

Applicants' traversal is based on that the combination of the references is not obvious. Applicants traversed the rejection based on that the '018 patent requires developing tolerance to the antibody by virtue of having a history of consumption of the antibody while the claimed invention does not require developing tolerance. Moreover, the "consisting essentially of" phrase has been ignored.

While Applicants differentiate the claimed invention from the reference based on the requirement of developing tolerance, the claimed invention is not limited to the method for administering an antibody to the population without developing the tolerance. Rather, the claimed invention is unpatentable over a combination of references that teach an oral administering of an avian antibody to C. perfringens solution in a subject. The combination of the '018 patent, Uemura and Merck reference does teach an oral administering of an avian antibody to C. perfringens solution in a subject.

In regards to the "consisting essentially of" phrase, it is true that MPEP 2111.03 indicates the "consisting essentially of" limits the claims to those steps specified and those steps that do not materially effect the basic novel characteristics of the claimed invention. However, in absent a clear indication the phrase is construed as equivalent to "comprising" (MPEP 2111.03). In the instant specification, there is no clear

definition of "consisting essentially of" unlike Applicants assert. p. 6 of the instant specification discloses what encompasses the claimed invention (lines 13-22) but no indication of consisting essentially of.

Furthermore, Applciants argue that there is no motivation to combine the reference because the ordinary skilled in the art would use the antibiotics for infections and no one would use the time consuming antibody method as in the '018 patent. The Merck reference was provided to support the clostridial infections are mainly caused by the tetani, perfringens, or difficile species (p. 1176, of record). Moreover, the neutralization of toxins, antitoxin is used (p. 1178, of record, in particular). Therefore, it is obvious to combine the references.

6. Upon further consideration, the following new rejection is set forth herein.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1, 3-13 and 15-20 are rejected under 35 U.S.C. 112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The step (b) of the claims 1, 8 and 15 are duplicate of step (a)(ii) in providing administrable solution. Appropriate correction is required.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1, 5-8, 11-13, 15 and 18-20 are rejected under 35 U.S.C. 103 as being unpatentable over U.S. Pat. No. 4,689,299 in view of U.S. Pat. No. 4,550,019.

The '299 patent teaches an oral administration or delivery of a monoclonal antibody to Clostridium perfringens in an individual (col. 16, lines 17-40, Table 1, in particular). The '299 patent teaches that the administration can be therapeutic as well as preventive (col. 11-12, in particular).

The '299 patent does not teach avian antibodies as in claim 1.

However, the '019 patent teaches the avian antibodies are more practical and convenient source for a wide variety of antibodies for anti-tetanus, anti-venines and anti-toxins (col. 4, lines 46- col. 5, lines 34, in particular)..

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make avian antibodies as taught by the '019 patent with the Clostridium perfringens antibody taught by the '299 patent.

One of the ordinary skill in the art would have been motivated to do so because producing avian antibody provides more convenient, practical source for antibodies of a wide variety and the process is less time consuming.

From the teachings of reference, it would have been obvious to one of ordinary skill in the art would have a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

11. Claims 3, 4, 9, 10, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 4,689,299, U.S. Pat. No. 4,550,019 as applied to claims 1, 5-8, 11-13, 15 and 18-20 above, and further in view of U.S. Pat. No. 4,748,018.

The teachings of the '299 and '019 patents have been discussed, supra.

The '299 and the '019 patent do not teach use of the solution in the form of nutritional/infant formula as in claims 3, 4, 9, 10, 16 and 17.

However, the '018 patent teaches the mix of antibody in the feeding stage or administration stage in the form of premixed food products (col. 9, lines 4-14, in particular).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to mix the avian antibody to Clostridium perfringens as taught by the '299 and the '019 patents in the premixed food product as taught by the '018 patent.

One of the ordinary skill in the art would have been motivated to do so because the mix of avian antibody to the premixed food products is handy and more convenient in handling large quantity of animals.

From the teachings of reference, it would have been obvious to one of ordinary skill in the art would have a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

12. No claims are allowable.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on M-F,9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Yunsoo Kim
Patent Examiner
Technology Center 1600
January 2, 2008

Maher M. Haddad

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PRIMARY EXAMINER